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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,414	05/24/2002	Masashi Kawanishi	61765.00385	9086
22907	7590	12/03/2003	EXAMINER	
BANNER & WITCOFF 1001 G STREET N W SUITE 1100 WASHINGTON, DC 20001			FORD, JOHN M	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/030,414

Applicant(s)

KAWANISHI ET AL.

Examiner

John M Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1--9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, and 4--8 is/are rejected.
- 7) ☒ Claim(s) 3 and 9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_

The claims in the application are claims 1—9.

Claim 1 is rejected under 35 U.S.C. 112, 1<sup>st</sup> and 2<sup>nd</sup> paragraph.

(A) alkyl, alkenyl, cycloalkyl, aryl, and heterocycle, alone or in combined terms, throughout the claim are not limited from infinity in their carbon size. This is a pharmaceutical taken by mouth. Very large hydrocarbons would be tars and waxes.

Heterocyclic is a huge area of Chemistry that completely overshadows formula II.

The heterocyclic term is not set forth in clear, specific language. The reader must produce the heterocyclic ring, in question.

Judge Smith noted many different definitions for aryl in the footnotes of In re Sus, 134 USPQ 301. It, therefore, becomes necessary for applicant to indicate in the claims what they intend by aryl. Heterocyclic, likewise, means many different things to different people. Some definitions of heterocyclic include B, P and As as hetero atoms. The U.S.P.T.O. does not consider those heterocyclic, and does not classify those patents as hetero rings. What applicants intend need be found in the claim.

The specification serves various purposes, it sets forth the prior art, that which applicants found unsuccessful, a defensive publication, that which applicants decided not to claim, or compounds that stop the infection, but kill the patient. The reader cannot tell the extent of the new invention, unless it is clearly

set forth in the claims, out of the mixed pieces of information of the specification.

The claims have to clearly set out that which is claimed.

The heterocyclic term is not acceptable, as it reads on heterocyclic rings that require specific conception by the reader. Specific, producible, heterocyclic rings are not set forth in the claims. The source of the starting materials for the combinations claimed is not set forth.

Exactly what ring is being claimed <sup>need</sup> be set forth in the claim.

Conception of what the intended heterocyclic rings, may be, should not be left to the reader.

Where is, what is intended by applicant, supported in the specification with sufficient representative exemplification? Note United Carbon Co. vs. Binney Smith Co. 55 U.S.P.Q. 381, Supreme Court of the United States (1942) "an invention must be capable of accurate definition, and it must be accurately defined to be patentable", above at 386.

Assuming that applicant is claiming what he regards as his invention, there are in reality only two basic reasons for rejecting claims under 35 U.S.C. 112; first is that language used is not precise enough to provide a clear-cut indication of scope of subject matter embraced by claim; this ground finds its basis in <sup>the</sup> second paragraph of section 112; second is that language is so broad that it causes <sup>the</sup> claim to have a potential scope of protection beyond that which is justified by specification disclosure; this ground stems from first paragraph of

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section 112. ~~M~~<sup>Merits</sup> of language in claim must be tested in light of these two requirements.

The heterocyclic variable is not precise and definite enough to provide a clear-cut indication of the scope of the subject matter embraced by the claim.

The heterocyclic concept is so broad that <sup>it</sup> ~~cause~~<sup>that</sup> the claim to have a potential scope of protection beyond ~~which~~<sup>that</sup> which is justified by the specification disclosure.

The written description is considered inadequate, ~~here~~<sup>here</sup> in the specification. Conception should not be the role the reader. Applicants should, in return for a 17/20-year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely an invitation to experiment. This is a 35 U.S.C. 112, first and second paragraph rejection. If you (the public) find that it works, ~~I~~<sup>I</sup> claim it, is not a proper basis for patentability. In re Kirk, 153 U.S.P.Q. 48 at page 53.

The heterocyclic rings possible is wide open to staggering possibilities.

Applicants place too much conception with the reader. The heterocyclic expression leaves open, which ones: Azines, Diazine, Triazines, Tetrazines. Where are the starting materials in the specification? Adjacent O and S are too strained to be produced.

One needs to know exactly, where, in the ring, the hetero atoms are: 1,2, or 1,3 or 1,4 or 1,2,4 or 1, 3, 4, etc., as each is a different entity, with a separate search.

These are compound claims, one must clearly know what is being claimed.

One, on reading the indication of heterocyclic applied by applicant, has no idea where the hetero atoms are in this unknown ring.

What are the hetero atoms?

Not all heterocyclic rings have been shown to be producible, as stable, at room temperature. What is the source of the starting materials? Where is the adequate representative exemplification in the specification to support the claim language?

The heterocyclic term presents a problem of lack of clear claiming, and support in the specification for the variables sought.

This rests conception with the reader.

What exactly is intended, and where is that supported in the specification.

Not a fair burden in return for applicants receiving a 17/20-year monopoly.

The possible combinations of any number of hetero atoms, in any combination, in multiple size rings is quite large, and not shown by applicants to be available starting materials.

A Markush listing of intended, conceived of, producible, heterocyclic rings is what is needed here. It is not possible to classify and search the molecule, unless one knows exactly which heterocyclic ring is being claimed.

The ultimate utility here is a pharmaceutical use. Declarations of unexpected results are often presented in the pharmaceutical arts. Applicants'

breadth of heterocyclic produces many different heterocyclic rings that could affect results.

Applicants need to claim what they have demonstrated as a specific fact.

The heterocyclic expressions in claim 1 are not acceptable, as they do not indicate, exactly, clearly, and specifically, what heterocyclic ring is being claimed. These expressions rest specific conception with the reader, and the specification does not include the source of the starting material for the rings which applicant now claims. One must be able to tell from a simple reading of the claim what it does and does not encompass.

Why? Because that compound claim precludes others from making, using, or selling that compound for 17/20 years. Therefore, one must know what compound for 17/20 years. Therefore, one must know what compound is being claimed.

The claims measure the invention, *United Carbon Co. Vs. Binney & Smith Co.*, 55 U.S.P.Q. 381 at 384, col. 1, end of first paragraph, Supreme Court of the United States (1942).

The U.S. Court of Claims held to this standard in *Lockhead Aircraft Corp. Vs. United States*, 193 U.S.P.Q. 449, "Claims measure the invention and resolution of invention must be based on what is claimed".

The CCPA in 1978 held "that invention is the subject matter defined by the claims submitted by the applicant". "We have consistently held that no applicant should have limitations of the specification read into a claim where no express

statement of the limitation is included in the claim"; In re Priest, 199 U.S.P.Q. 11, at 15.

Heterocyclic is too broadly stated in R28 and R30 in claim 1, see In re Wiggins, 178 U.S.P.Q. 421.

The heterocyclic expression includes adjacent O/S combinations that are un~  
stable.

The claim cannot be completely searched, here, until we know what heterocyclic means.

Similarly, the USPTO only recognizes: C,N,O,S,Se or Te as atoms of a heterocyclic ring. Therefore, there is a need for applicants to indicate what they mean by heterocyclic.

Heterocyclic is not just a substituent; it is a whole body of art, larger than the genus claimed here. Researchers often spend their entire life on hetero N heterocyclic compounds without ever getting to hetero O or hetero S compounds. Many heterocyclic compounds, within the claim, have never been made.

Accordingly, claim 1 is rejected under 35 U.S.C. 112, 1<sup>st</sup> and 2<sup>nd</sup> paragraphs. What is being claimed? Where is the adequate representative exemplification in the specification?

Claims 2, 7, 8 are rejected for the reasons claim 1 is rejected.

In an area of high interferences, you have to think what happens after the application is allowed. Counts are impossible to construct where there is no



specific support in the specification for the term as species; In re Ruschig, 154 USPQ 118.

A count cannot be constructed for heterocyclic, as it has no species support; Freerksen vs. Gass, 21 USPQ (2<sup>nd</sup>) 2007.

Claim 13 is not properly dependent on claim 1. No claim dependency is set forth in claim 13, so the reader has no idea what the active compounds are.

Claims 4 and 5 and 6 are rejected as being dependent on a non-allowable claim.

Claims 3 and 9 are objected to, as being dependent on a rejected claim.


A one-page Abstract is requested that only has on the page, the Abstract,

In claim 1, penultimate line, it is assumed that hydrido is hydrogen. Same, claim 2.

Accordingly to the PCT Search, WO 96.37485 is an X reference. Please Explain, *away*.

J. M. Ford:jmr

November 26, 2003

  
JOHN M. FORD  
PRIMARY EXAMINER  
GROUP - ART UNIT 1624